



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/450,609	11/30/99	WEIBEL	H 5739,200-US

HM12/1122
STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE
SUITE 6400
NEW YORK NY 10174-6400

EXAMINER

KIM, J

ART UNIT	PAPER NUMBER
----------	--------------

1617 //

DATE MAILED:

11/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/450,609

Applicant(s)

WEIBEL ET AL.

Examiner

Jennifer M Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3-5 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

Application/Control Number:

Page 2

09/450,609

Art Unit: 1617

DETAILED ACTION

The request filed on October 31, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/450,609 is acceptable and a CPA has been established. An action on the CPA follows.

The claims remain rejected for reasons of record set forth in Office Action dated May 1, 2000.

No further arguments are presented and the Examiner's rejection of claims 1-2 and 6-16 is deemed proper in the Office Action of ~~May~~ ^{June} 1, 2000 which is incorporated herein as follows:

Applicants' election without traverse of Group I, claims 1,2 and 6-16, drawn to pharmaceutical compositions in Paper No. 7 is acknowledged.

The claims have been examined only to the extent of applicants' election.

09/450,609

Art Unit: 1617

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are improper Markush group. They need to be rewritten by inserting "or" at the end of line 14 and line 30 respectively.

Claim Rejections - 35 USC § 102

II. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

09/450,609

Art Unit: 1617

III. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lohray et al. (WO 9741097) disclosed by applicants and applicants' admission.

Applicants admit, at page 1, lines 7-11 of the specification, that applicants' active agent and pharmaceutically acceptable salts has been found useful in the treatment of type 2 diabetes acting as a insulin sensitizer as disclosed in WO9741097. Lohray et al. also teach at page 35, example, applicants' composition in a tablet form.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

09/450,609

Art Unit: 1617

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al.(WO 9741097) in view of Sohda et al.(U.S.Patent No.5972971).

Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent (see previous rejection) in tablet, capsule, or powder form, in combination with the pharmaceutically acceptable excipient set forth in claim 8-10, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions.

Sohda et al. at abstract and column 10, lines 20-21, teach anti-diabetic agent containing anti-oxidants, preferably ascorbic acid. Sodha et al. also teach at column 9, lines 55-65, the anti-diabetic agent containing applicants' excipient such as lactose, mannitol, starch, crystalline cellulose, silicone

09/450,609

Art Unit: 1617

dioxide, magnesium stearate, and hydroxy propyl methyl cellulose.

The difference between the primary reference and applicants' claimed invention is the presence of anti-oxidant set forth in claims 6,14, and 15, and the proportions set forth in claims 8 and 9. However, to incorporate anti-oxidant to the primary reference would have been obvious to a person of ordinary skill in view of Sohda et al. who teach antidiabetic agent containing anti-oxidant and the other excipient. One in ordinary skill in the art would have been motivated to combine anti-oxidants to the above composition since Lohray et al. teach other media normally employed can be incorporated and anti-oxidant is normally incorporated by Sohda et al. in formulating anti-diabetic agent.

The proportions of active agents to be used, and adjusting water content of excipient are all deemed obvious since they are all within the knowledge of the skilled pharmacologist.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

09/450,609

Art Unit: 1617

None of the claims are allowed.


It is suggested, to advance the prosecution of the subject application, that a side by side comparison of stability be performed and results submitted per Rule 1.132 for review by the Patent Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

jmk
November 9, 2000


Theodore J. Criares
Primary Examiner
Art Unit 1617